Queen’s University at Kingston (“Queen’s”) implementation of the United States Federal Awarding Agencies’ (excluding Public Health Services agencies) Conflicts of Interest Policy in accordance with Regulations 2 CFR Part 200

<table>
<thead>
<tr>
<th>Queen’s Office of Administrative Responsibility</th>
<th>University Research Services (URS) under the purview of the Vice Principal (Research) portfolio</th>
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<tr>
<td>Designated Official</td>
<td>Executive Director, Research Operations and Strategy (or designate)</td>
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<td>Scope &amp; Purpose</td>
<td>Applicable to all Investigators applying for and/or receiving funding from the Federal Awarding Agency or working on a project funded by the Federal Awarding Agency so as to promote objectivity in research and to ensure research is free from bias, as required under US Regulations 2 CFR Part 200</td>
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Overview
This procedure is made under the Queen’s University Senate Policy on Integrity in Research and the Queen’s University Research Administration Policy.

United States (US) regulation 2 CFR Part 200 at section 112 specifies:

The Federal awarding agency must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy.
In addition, regulation 2 CFR Part 200.303 imposes obligations on Queen’s as follows:

The non-Federal entity must:

(a) Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award. These internal controls should be in compliance with guidance in “Standards for Internal Control in the Federal Government” issued by the Comptroller General of the United States or the “Internal Control Integrated Framework”, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

(b) Comply with Federal statutes, regulations, and the terms and conditions of the Federal awards.

(c) Evaluate and monitor the non-Federal entity's compliance with statutes, regulations and the terms and conditions of Federal awards.

(d) Take prompt action when instances of noncompliance are identified including noncompliance identified in audit findings.

(e) Take reasonable measures to safeguard protected personally identifiable information and other information the Federal awarding agency or pass-through entity designates as sensitive or the non-Federal entity considers sensitive consistent with applicable Federal, state, local, and tribal laws regarding privacy and obligations of confidentiality.

Further, regulation 2 CFR Part 200.318(c)(1) states:

The non-Federal entity must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award and administration of contracts. No employee, officer, or agent may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract. The officers, employees, and agents of the non-Federal entity may neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts. However, non-Federal entities may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the non-Federal entity.

In order to be eligible to apply for, receive and/or hold a Federal Award from a Federal Awarding Agency, in compliance with 2 CRF Part 200 (the “Regulation”), Queen’s is implementing the process contained herein and in the associated Disclosure Form to collect and potentially disclose Financial Conflicts of Interest to applicable Federal Awarding Agencies. As an employee of Queen’s engaged in the administration of a contract supported by a Federal Award, you are subject to the Regulation.

In certain circumstances, such as where there is a determination of a Financial Conflict of Interest or a failure to disclose a Significant Financial Interest, the Federal Awarding Agency may require some form of public reporting. Accordingly, if you elect to apply for, receive and hold the Federal Awarding Agency’s award, you must comply with the Regulation and you will then be asked to sign and return the attached disclosure and consent form. This form will allow Queen’s to provide the reports required by the Regulation to the applicable Federal Awarding
Agency and, if required, make the information publicly available. Please read the disclosure and consent form carefully and see parts 3 & 4 below for more information regarding this.

You may opt out of complying with the Regulation, however this will mean that the Federal Award must be returned to the Federal Awarding Agency (if already received), or you must relinquish the grant if the Federal Award has not yet been received. The Federal Awarding Agency requires compliance by all recipients as a condition of any Federal Award and Queen’s has no ability to remove this condition from the terms of the Federal Award.

The requirements of the Regulation only apply to funding applications / awards from a Federal Awarding Agency and are in addition to any Queen’s established policies and procedures or collective agreement provisions regarding conflicts of interest.

Purpose

The purpose of this implementing procedure is:

(a) To clarify the Federal Awarding Agency’s reporting requirements regarding reporting of Significant Financial Interests (SFI) by Investigators at Queen’s;
(b) To outline the process in compliance with the Federal Awarding Agency’s requirements, by which the Designated Official confirms whether the SFI is connected to an Investigator’s institutional responsibilities, and assesses whether it is a Financial Conflict of Interest (FCOI) for a project funded by the Federal Awarding Agency; and
(c) To outline the Federal Awarding Agency’s expectations of the Designated Official, Queen’s and an Investigator in managing and reporting FCOIs to the Federal Awarding Agency, in order to comply with the Regulation.

Procedure

1. Reporting by Investigators
2. Assessment and record-keeping by the Designated Official
3. Requirements Regarding Management and Reporting of a FCOI
4. Agency Requirements: Sub Contracting and Public Accessibility of Information
5. Non-Compliance
6. Definitions
7. Declaration by Investigator
8. Disclosure & Consent by Investigator

1. REPORTING BY INVESTIGATORS

1.1 Who Must Disclose: All Investigators who are:
   • applying for and/or receiving funding from a Federal Awarding Agency; or
   • working as an Investigator on a project funded by a Federal Awarding Agency,

whether directly or through a subcontract, must disclose any SFI in writing to the Designated Official. See the Definitions section at part 6 to assist you in understanding what a Federal Awarding Agency considers to be a SFI.

In order to comply with the Federal Awarding Agency, Queen’s requires disclosure of any SFI (including any SFI held by the Investigator’s spouse or dependent children) to be made at the following times:
(a) **Initial Disclosure:** the initial disclosure must:
   (i) be made at least 30 days before the time of the application to the Federal Awarding Agency; or
   (ii) at any time prior to the receipt of a Federal Award; and
   (iii) include all SFI’s in the 12 months preceding the application to the Federal Awarding Agency.

(b) **Ongoing Disclosure:** In compliance with the Federal Awarding Agency directives, Queen’s requires ongoing disclosure at the following periods:
   (i) within 30 days of discovering or acquiring (including but not limited to a purchase; marriage; inheritance, etc.) a new SFI; and
   (ii) on an annual basis during the term of the Federal Awarding Agency funded research. This includes providing updated information on a previously disclosed SFI.

(c) **New to Queen’s:** All Investigators who are new to Queen’s and are applying for and/or receiving funding from a Federal Awarding Agency at Queen’s, or who are participating as an Investigator in a Federal Awarding Agency-funded research project at Queen’s, must make the initial disclosure and ongoing disclosures noted above.

1.2 **Steps to Disclose a Significant Financial Interest:** To disclose a SFI to Queen’s:
   (a) the Investigator, on behalf of themselves; their spouse; or dependent children must complete the Disclosure and Consent Form for Significant Financial Interests attached to this Information Memorandum and return it to the Designated Official.

   As discussed in the Overview above the disclosure and consent form(s) attached to this Information Memorandum include the right for Queen’s to notify the Federal Awarding Agency, and provide to the Federal Awarding Agency any reports it may require pursuant to the provisions of the Regulation. Additionally, the disclosure and consent form(s) will allow Queen’s to make certain information publicly available, as required by the Regulation or the Federal Awarding Agency.

2. **ASSESSMENT OF DISCLOSURES AND RECORD-KEEPING BY DESIGNATED OFFICIAL**

2.1 In keeping with the requirements of the Regulation, the Designated Official must review all disclosures of SFI’s from Investigators, including sub recipient Investigators, within the timeframes noted below and to determine whether or not:

   (a) the disclosure is related to the Federal Awarding Agency funding

   The SFI is related to Federal Awarding Agency funded research if the Designated Official may reasonably determine that the SFI:
   (i) could be affected by the Federal Awarding Agency-funded research; or
   (ii) is in an entity whose financial interest could be affected by the research.

   The Designated Official may involve the Investigator in the Designated Official’s determination of whether or not a SFI is related to Federal Awarding Agency-funded research.

   (b) each SFI is a FCOI

   A FCOI exists when Queen’s, through its Designated Official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Federal Awarding Agency-funded research.
2.2 The review and determination noted above must be conducted by the Designated Official at the following times:

(a) prior to Queen’s expenditure of any funds under a Federal Awarding Agency-funded research project. This means that your research account may not be authorized until after the Federal Awarding Agency’s requirements on disclosure and assessment have taken place.

(b) within 60 days of disclosure, whenever, in the course of an ongoing Federal Awarding Agency-funded project, an Investigator or sub recipient Investigator who is new to participating in the project, discloses a SFI or an existing Investigator or sub recipient Investigator discloses a new SFI to Queen’s; and

(c) within 60 days whenever Queen’s identifies a SFI that:
   (i) was not disclosed in a timely manner by an Investigator or sub recipient Investigator; or
   (ii) for whatever reason, was not previously reviewed by the Designated Official during an ongoing Federal Awarding Agency-funded project.

2.3 Record Keeping: the Designated Official must maintain records relating to: (a) all Investigator disclosures of SFIs and Queen’s review of, and response to, such disclosures (whether or not a disclosure resulted in the determination of a FCOI); (b) all actions taken by Queen’s under the Regulation and the Federal Awarding Agency’s policy; and (c) any retrospective review related to the SFI and/or FCOI (if applicable). Queen’s shall keep the records for at least 3 years from the date the final expenditures report is submitted to the Federal Awarding Agency, the date of final payment; or where applicable, for other time periods specified by the Federal Awarding Agency.

2.4 The Federal Awarding Agency may inquire at any time (before, during or after a Federal Award) into an Investigator’s disclosure of financial interests and Queen’s review of, and response to, such disclosure, whether or not the disclosure resulted in Queen’s determination of a FCOI. This includes situations in which an Investigator moves from one university to another.

2.5 Queen’s may be required to submit to the Federal Awarding Agency, or permit the Federal Awarding Agency to conduct on site to review of, all records pertinent to compliance with the Regulation.

3. REQUIREMENTS REGARDING MANAGEMENT AND REPORTING OF FCOI

3.1 If the Designated Official determines that there is a FCOI, the Designated Official will prepare a FCOI management plan to manage the FCOI. Key elements of the management plan include:
   • role and principal duties of the conflicted Investigator;
   • conditions of the management plan;
   • how the management plan is designed to safeguard objectivity in the research project;
   • confirmation of the Investigator’s agreement to the management plan;
   • other information as needed.

3.2 Once the management plan is in place,
   (a) the Investigator is required to comply with the management plan prescribed by the Designated Official; and

   (b) on behalf of Queen’s, the Designated Official must monitor compliance with the management plan on an
ongoing basis until the completion of the project.

3.3 **Agency Reporting Requirements**: Queen’s, through its Designated Official, must provide initial and ongoing FCOI reports to the Federal Awarding Agency as applicable:

(a) after a Federal Award is granted but prior to any expenditure of any funds;

(b) annually at the same time as the annual progress report issue:

For any FCOI previously reported to the Federal Awarding Agency, the report must address the status of the FCOI and any changes to the management plan for the duration of the Federal Awarding Agency-funded research project. The annual FCOI report must specify whether the financial conflict is still being managed or explain why the FCOI no longer exists.

(c) in the time and manner specified by the Federal Awarding Agency for any other FCOI reports for the duration of the project period (including extensions with or without funds).

(d) sub recipients: Queen’s must provide FCOI reports to the Federal Awarding Agency regarding all FCOI’s of all sub recipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

FCOI reports must include sufficient information to enable the Federal Awarding Agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of Queen’s management plan. Each FCOI report prepared by the Designated Official must contain:

- the grant number;
- project director/principal investigator or contact project director/principal investigator if a multiple project director/principal investigator model is used;
- name of Investigator with FCOI;
- name of the entity with which the Investigator has a FCOI;
- nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
- value of the financial interest per year:
  - $0 - $4,999;
  - $5,000 - $9,999;
  - $10,000 - $19,999;
  - amounts between $20,000 and $100,000 by increments of $20,000;
  - amounts above $100,000 by increments of $50,000;
  - a statement that a value cannot be readily determined.
- a description of how the financial interest relates to the Federal Awarding Agency-funded research and the basis for Queen’s determination that the financial interest conflicts with such research; and
- key elements of Queen’s management plan.

4. **AGENCY REQUIREMENTS: SUB CONTRACTING AND PUBLIC ACCESSIBILITY OF INFORMATION**

4.1 **Sub Contracting**: if Queen’s carries out Federal Awarding Agency-funded research through a sub recipient, then Queen’s must take reasonable steps to ensure that any sub recipient Investigator complies with the Regulation by:
(a) incorporating, as part of the written agreement with sub recipient, terms that establish whether the Regulation as implemented at Queen’s will apply, or whether the sub recipient has its own FCOI policy that will apply to the sub recipient’s Investigators;

(b) incorporating a provision whereby the sub recipient warrants that its FCOI policy complies with the Regulation and any other regulations or policies applicable to the Federal Awarding Agency, if the sub recipient elects to follow its own FCOI policy; or

(c) incorporating a provision whereby the sub recipient Investigators must comply with the implementation of the Regulation at Queen’s. If this is agreed between the parties then Queen’s must obtain a written agreement specifying time periods for the sub recipient to submit all Investigator disclosures of SFI’s to Queen’s. Such time periods must be sufficient to enable Queen’s to comply in a timely fashion with its review, management and reporting obligations required by the Federal Awarding Agency.

4.2 Public Accessibility of Information: Subject to a Federal Awarding Agency’s requirements, Queen’s will:

(a) maintain an up-to-date, written, enforced policy (and associated procedures) on financial conflicts of interest that comply with the Federal Awarding Agency’s regulations and make such policy available via a publicly accessible website; and may

(b) make available, via publicly accessible website or in writing within 5 business days of any request, the information listed in part 4.3(c) below concerning any SFI that meets the criteria below in this part 4.3(b) (Note that Queen’s must do this prior to the expenditure of any award funds):

- SFI was disclosed and is still held by the Investigator who has been identified by Queen’s as an Investigator for the Federal Awarding Agency-funded research project in the grant application, contact proposal, contract, progress report, or other required report submitted to the Federal Awarding Agency;
- Queen’s determines that the SFI is related to Federal Awarding Agency-funded research; and
- Queen’s determines that the SFI is a FCOI;

and/or

(c) post on the publicly accessible website, or make available in response to written requests, the following minimum information:

- Investigator’s name;
- Investigator’s position with respect to the research project;
- nature of the SFI;
- approximate dollar value of the SFI;
  - $0 - $4,999;
  - $5,000 - $9,999;
  - $10,000 - $19,999;
  - amounts between $20,000 and $100,000 by increments of $20,000;
  - amounts above $100,000 by increments of $50,000; or
  - a statement that a value cannot be readily determined,
- the entity with which the Investigator has a FCOI,

to enhance transparency and accountability in accordance with the Agency’s requirements; and

(d) update the above-noted information in part 4.3(b) and (c), within 60 days or becoming aware of any changes to the information and, at a minimum, shall update the information annually and maintain the
availability of the information for at least 3 years from the date that the information was most recently updated.

5. **NON-COMPLIANCE**

5.1 Non-compliance with the Regulation may constitute misconduct in relation to Federal Awarding Agency-funded research. The Regulation requires Queen’s to report any event of non-compliance with Agency-funded projects. Queen’s is obliged to follow the Regulation and any Federal Awarding Agency requirements and recommendations if there is Investigator non-compliance. Queen’s may also review any non-compliance in accordance with relevant collective agreement(s); policies and regulations applicable to research at Queen’s.

6. **DEFINITIONS**

The following is a synopsis of definitions applicable to this Procedure:

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<th>Investigator (Including Co-Investigator)</th>
<th>is the individual(s) a research organization designates as having an appropriate level of authority and responsibility for leading and directing the research intellectually and logistically, including the proper conduct of the research, the appropriate use of funds and administrative requirements such as the submission of scientific progress reports to the agency. (72 FR 54257 – 09/24/2007)</th>
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<th>Significant Financial Interest (SFI)</th>
<th>(1) <strong>financial interests</strong> A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:</th>
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<td>(a) <strong>publicly traded entity</strong> With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;</td>
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<td></td>
<td>(b) <strong>non-publicly traded entity</strong> With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or</td>
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<td>(c) <strong>intellectual property rights and interests</strong> Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests or upon the filing of a patent application, whichever is earlier.</td>
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<td>(2) <strong>sponsored travel</strong> Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not</td>
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reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by an US federal, state, or local government agency, an US institution of higher education, or an US academic teaching hospital, an US medical center, or an US research institute that is affiliated with an US institution of higher education. This disclosure will include, at a minimum:

(a) the purpose of the trip;
(b) the identity of the sponsor / organizer;
(c) the destination; and
(d) the duration.

The Designated Official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the Agency-funded research.

(3) (exclusions) The term SFI does not include the following types of financial interests:

(a) (salary or other remuneration paid by Queen’s) salary, royalties, or other remuneration paid by Queen’s to the Investigator if the Investigator is currently employed or otherwise appointed by Queen’s, including intellectual property rights assigned by Queen’s and agreements to share in royalties related to such rights;

(b) (investments out of Investigator’s direct control) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

(c) (teaching / lecture income affiliated with certain US entities) income from seminars, lectures, or teaching engagements sponsored by an US federal, state, or local government agency, and US institution of higher education, an US academic teaching hospital, an US medical center, or an US research institute that is affiliated with an US institution of higher education; or

(d) (service or advisory income affiliated with certain US entities) income from service on advisory committees or review panels for an US federal, state, or local government agency, an US institution of higher education, an US academic teaching hospital, an US medical center, or an US research institute that is affiliated with an US institution of higher education.

Designated Official
The individual appointed to this position at Queen’s, under the purview of the Vice Principal (Research).

Financial Conflict of Interest (FCOI)
A SFI that could directly and significantly affect the design, conduct, or reporting of Agency-funded research.
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<th>Disclose</th>
<th>An Investigator’s disclosure of SFI’s to Queen’s.</th>
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<td>Financial Interest</td>
<td>Anything of monetary value, whether or not the value is readily ascertainable.</td>
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<td>Federal Awarding Agency</td>
<td>The Federal agency that provides a Federal Award directly to a non-Federal entity; where an “agency” is defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f) and includes each authority of the Government of the United States, whether or not it is within or subject to review by another agency.</td>
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<td>Federal Award</td>
<td>Federal award has two definitions, which depend on the context of its use. Paragraphs (a) and (b) explain the context and define the term appropriately.</td>
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<td></td>
<td>a. (1) The Federal financial assistance that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in § 200.101 Applicability of the OMB Uniform Grant Guidance; or (2) The cost-reimbursement contract under the Federal Acquisition Regulations that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in § 200.101 Applicability of the OMB Uniform Grant Guidance.</td>
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<td></td>
<td>b. The instrument setting forth the terms and conditions. The instrument is the grant agreement, cooperative agreement, other agreement for assistance covered in paragraph (b) of § 200.40 Federal financial assistance of the OMB Uniform Grant Guidance, or the cost-reimbursement contract awarded under the Federal Acquisition Regulations. (c) Federal award does not include other contracts that a Federal agency uses to buy goods or services from a contractor or a contract to operate Federal government owned, contractor operated facilities (GOCOs). (d) See also definitions of Federal financial assistance, grant agreement, and cooperative agreement.</td>
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<tr>
<td>Non-Federal entity</td>
<td>A state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out a Federal award as a recipient or subrecipient.</td>
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<td>Pass-Through entity</td>
<td>Pass-through entity means a non-Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program.</td>
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<td>Manage</td>
<td>Taking action to address a FCOI, which may include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.</td>
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7. DECLARATION

I have read and understood this Information Memorandum entitled "Queen's implementation of the United States Federal Awarding Agencies' Conflicts of Interest Policy in accordance with Regulations 2 CFR Part 200".

I make the following declaration (check statements that apply):

☐ If I am the Principal Investigator and I wish to opt out of compliance with the Federal Awarding Agency’s Regulation. I hereby authorize Queen’s to advise the Federal Awarding Agency / Prime Recipient that I am unable to accept the award and or to negotiate with the Federal Awarding Agency to replace Queen’s Principal Investigator with a suitably qualified Investigator who is in a position to comply with the Regulation.

☐ If I am not the Principal Investigator and I wish to opt out of compliance with the Regulation, I hereby authorize Queen’s Designated Official to advise the Queen’s Principal Investigator that I cannot take part in the Federal Awarding Agency-funded research project and I understand the full ramifications of this choice.

☐ I agree to comply with the Regulation and will complete /have completed the following disclosure and consent form(s) (delete as necessary):
  - Disclosure & Consent Form on behalf of myself; my spouse and/or dependent child(ren);

☐ I understand and acknowledge that in addition to my obligations to the Federal Awarding Agency, Queen’s University also has obligations to the Federal Awarding Agency as set out in this document in relation to the Federal Award for which I am the Investigator.

☐ If I am the Principal Investigator under the Federal Award (for Agency-funded research conducted at Queen’s) I advise I have provided a copy of this Information Memorandum to the following Investigators (as that terms are defined by the Agency) at Queen’s, involved in the Federal Awarding Agency-funded research. Additionally, I confirm that I have instructed each Investigator to return their signed documentation directly to the Queen’s Designated Official.

  I understand this is an ongoing requirement and the Information Memorandum must be provided to any new Investigator during the term of the Federal Awarding Agency-funded research project.

  The names of the Investigators are (please list below):

__

Investigator Name:
Title:
Institution (if other than Queen’s):